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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/848,417   | 05/04/2001  | Ib Mendel-Hartvig    | 1614-0248P          | 7800             |
| 24256  | 7590        | 07/06/2004           | EXAMINER            |                  |
| DINSMORE & SHOHL, LLP<br>1900 CHEMED CENTER<br>255 EAST FIFTH STREET<br>CINCINNATI, OH 45202 |             |                      | NGUYEN, BAO THUY L  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1641                |                  |

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                    |                       |
|------------------------------|--------------------|-----------------------|
| <b>Office Action Summary</b> | Application No.    | Applicant(s)          |
|                              | 09/848,417         | MENDEL-HARTVIG ET AL. |
|                              | Examiner           | Art Unit              |
|                              | Bao-Thuy L. Nguyen | 1641                  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 May 2004.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

*Response to Amendment*

1. Applicant's amendment filed May 03, 2004 has been received. Claim 11 has been added. Claims 1-11 are pending.
2. The text of those US Codes not found in this office action may be found in a previous action.

*Rejections Withdrawn*

3. The rejection of claims 3, 4, 7 and 8 as being vague and indefinite is withdrawn in view of the amendments to the claims.
4. The rejection of claims 5 and 6 as being anticipated by May is withdrawn in view of the amendments to the claims.
5. The rejection of claims 1-5 and 10 as being anticipated by Kiser is withdrawn in view of the amendments to the claims and Applicant's arguments.

*Claim Rejections - 35 USC § 112*

6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague with respect to the placement of the time indicator (14). The time indicator is recited to be arranged at a variable position between the upstream and downstream ends of the wicking member thereby permitting variation of the time elapsing from the application of the liquid until the indicator substance changes color;

however, it is unclear how the elapsed time is *measured*. For example, if the time indicator is placed at location X, a predetermined distance from the sample application area, does it mean that anything applied to the application area will take Y amount of time to migrate thereto? If so, this phenomenon needs to be clearly recited.

***Response to Arguments***

7. Applicant argues that this claim is clear because the time indicator of the instant invention provides a confirmation that liquid applied to the liquid application zone has been transported through the detection zone to the wicking member and therefore that the assay is completed and the result may be read. The ability to vary the position of the time indicator between the upstream and downstream ends of the wicking member is important in that it allows the time elapsing from the liquid application to the indicator color change to be shortened or prolonged as desired.

This argument has been fully considered and while the explanation is true, it appears that Applicant has misunderstood the rejection, or alternatively, Applicant has redefined the term “time indicator” to a meaning that is not conventionally known. In either case, the claim is confusing.

While the claimed time indicator operates as explained by Applicant, i.e. that it confirms the end point of the assay, it does not actually indicate time which is how the claim has been interpreted. Time is defined by Webster’s dictionary as “*a number, as of years, days, or minutes, representing such an interval or a system by which such intervals are measured or such numbers are reckoned*”, and indicator is defined as “*a substance, as litmus or phenolphthalein, that indicates the presence, absence, or*

concentration of a substance or the degree of reaction between two or more substances by means of a characteristic change, esp. in color." In this way, the term "indicator" is accurate; however, the term "time" as used by Applicant does not mean a number. The use of the term "time indicator" is understood to mean an indicator that measures time; however, the indicator recited in the instant claim does not measure time, it only indicates that the end of the assay has been reached. The time that it takes for the liquid to reach the indicator is predetermined during a manufacturing process. Therefore, the use of the term "time indicator" in this context is vague and indefinite and does not allow the metes and bounds of the claim to be ascertained.

*Claim Rejections - 35 USC § 102*

8. Claims 1-4 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al (US 5,602,040) for reasons of record in the previous office which are reiterated herein below.

May teaches an assay device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier. The device contains a labeled specific binding reagent for an analyte. The labeled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte, which unlabeled reagent, is permanently immobilized in a detection zone on the carrier material. (Column 2, lines 3-20). May teaches an embodiment where the device contains a control zone loaded with an antibody that will

bind to the labeled antibody from the first zone; or the control zone can contain an anhydrous reagent that when moistened, produces a color change or color formation.

(Column 5, lines 8-27) May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (column 3, lines 22-32). May teaches a plurality of detection zones arranged in series on the porous solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or can be loaded individually with different specific binding agents to provide a multi-analyte test (column 9, lines 19-30). Quantitative measurement may be done visually by eye or by instrument. May teaches backing the porous nitrocellulose sheet with plastic to increase handling strength (column 7, lines 15-20). Specifically, May teaches laminating the porous carrier to a transparent moisture-impermeable plastic material and that the transparent strip is in contact with the upper inner surface of the casing (column 14, lines 33-41). May also teaches an absorbent sink provided at the distal end of the carrier material to aid in the flow of sample and to ensure that excess labeled reagent from the first zone which does not participate in any binding reaction in the second zone is flushed away from the detection zone (column 5, line 58 through column 6, line 6). May teaches that the flow rate characteristics of the porous carrier material can be selected to allow adequate reaction times during which the binding reaction can occur. Controls over these parameters can be achieved by the incorporation of viscosity modifiers such as sugars and modified celluloses to slow down the reagent migration (column 7, lines 30-39).

*Response to Arguments*

9. Applicant's arguments filed May 03, 2004 have been fully considered but they are not persuasive.

Applicant argues that May does not anticipate the instant invention because May fails to teach a time indicator arranged in contact with the wicking member at a variable position thereby permitting variation of the time elapsing from the application of liquid to the liquid application zone until the indicator substance or substance combination changes color. Applicant argues that the control zone of May (i.e. time indicator) may not be variably arranged downstream of the detection zone and that May does not teach means for viewing a time indicator placed anywhere other than at a relatively small observation window.

These arguments have been fully considered but are not deemed persuasive. May teaches the same device of the instant invention. May does not specifically use the term "time indicator", however, may teaches the same means for indicating the end of the assay, i.e. a control zone comprising a dye. As explained above, the term "time indicator" as used by Applicant does not indicate or measure "time". Specifically, Applicant asserts that the time indicator provides a confirmation that liquid applied to the liquid application zone has been transported through the detection zone to the wicking member and therefore that the assay is completed and the result may be read (Amendment dated April 29, 2004, page 5, last sentence). As such, May teaches the same means for determining completion of the assay. See May column 5, lines 8-27.

Applicant argues that the time indicator of the instant invention is arranged in contact with the wicking member at a variable position, and that the time indicator has a

wide range of positions along the wicking member as depicted in figure 3. Applicant asserts that May does not teach or suggest this feature.

This argument has been fully considered but is not persuasive. The term variable means changeable (i.e. capable of being changed or moved; however, since the claims are directed to a *product* and not a *method of making the product*, and since the claims do not specifically state that the time indicator would be changed or moved in the device, the time indicator, as claimed is seen to be an end-point indicator placed in a specific location to indicate the end of an assay. The feature that enables the time indicator to be arranged in different locations on the wicking member appears to be accomplished during manufacture of the device, thus, it is not a limitation of the device itself. Furthermore, because May teaches that spatial separation between the various zones, and the flow rate characteristics of the porous carrier material (i.e. wicking membrane), can be selected to allow adequate reaction times during which the necessary specific binding can occur, and to allow the labeled reagent in the first zone to migrate through the carrier (column 7, lines 30-39), May clearly recognizes and teaches variable positioning of the reagents including the dye indicator.

#### *Claim Rejections - 35 USC § 103*

**10.** Claims 7-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over May et al (US 5,602,040).

May differs from the instant invention in failing to specifically teach that the time indicator substance is applied to wicking member or to a support which is in turn applied to the wicking member. However, May specifically teaches that the absorbant

sink (i.e. wicking member) is either chromatography paper applied to the porous solid phase, or a length of porous solid phase material that extends beyond the detection zone (column 6, lines 1-6). May also teaches that the control zone (i.e. time indicator) is located downstream from the detection zone (column 5, lines 8-26), therefore, it can clearly be seen that the time indicator taught by May is located directly on the wicking member, or as an alternative, it is located on the wicking member and the wicking member is disposed on the test strip.

**11.** Claims 5 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Gattiglia (US 6,655,315 B1).

See the discussion of May above. May teaches an embodiment where a moisture-absorbant material such as silica gel is included in the device to maintain the strip in the dry state. See column 12, lines 40-43. However, May differ from the instant invention in failing to teach that the silica gel may be used as an assay end-point indicator.

Gattiglia discloses novel silica gel for use as indicator labels in chemical products. Gattiglia teaches that silica gel, with copper chloride as active principles in combination with a mixture of hygroscopic salts, changes color when wet and are advantageously used as a moisture indicator. See columns 1 and 2. Gattiglia teaches that the indicator labels may be soaked or sprayed onto a paper support.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention is made to use the indicator labels-soaked support taught by Gattiglia in the device of May because both May and Gattiglia teaches that is necessary to have means that can maintain and indicate the moisture conditions inside chemical

packaging. Furthermore, the use of the indicator labels taught by Gattiglia in the device of May would have provided the advantage of a dual function, i.e. one that can maintain the device in a dry condition and also serve to notify the user that liquid applied to the device has migrated to the end-point assay indicator.

*Response to Arguments*

**12.** Applicant's arguments filed May 03, 2004, with respect to the Kiser reference have been fully considered and are persuasive. The rejection of claims 1-5 and 10 has been withdrawn.

**13.** All other arguments have been addressed above.

*Conclusion*

**14.** The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,075,078

US 5,229,073

US 5,415,994

**15.** Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**16.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641